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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,427	05/31/2005	Marco Emilio Bianchi	1014-PCT-US	6913

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EXAMINER

SGAGIAS, MAGDALENE K

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,427

Applicant(s)

BIANCHI ET AL.

Examiner

Magdalene K. Sgagias

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-18 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 7-8, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof for the treatment of tissue damage and/or to promote tissue repair and regeneration.

Group II, claim(s) 1-5, 7-8, drawn to a composition comprising a HMGB1 expressing vectors, for the treatment of tissue damage and/or to promote tissue repair and regeneration.

Group III, claim(s) 1-6, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof and further comprising an effective amount of an anti-inflammatory agent for the treatment of tissue damage and/or to promote tissue repair and regeneration

Group IV, claim(s) 1-6, drawn to a composition comprising a HMGB1 expressing vectors and further comprising effective amount of an anti-inflammatory agent for the treatment of tissue damage and/or to promote tissue repair and regeneration.

Group V, claim(s) 1-10, drawn to a composition comprising an effective amount of the HMGB1 protein or functional parts thereof and further associated to stem cells for the treatment of tissue damage and/or to promote tissue repair and regeneration.

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Group VI, claim(s) 1-10, drawn to a composition comprising a HMGB1 expressing vectors and further associated to stem cells, for the treatment of tissue damage and/or to promote tissue repair and regeneration.

Group VII, claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 antibodies for the treatment of adverse effects induced by necrotic tissue.

Group VIII, claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 interference RNAs for the treatment of adverse effects induced by necrotic tissue.

Group IX, claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 antisense RNAs for the treatment of adverse effects induced by necrotic tissue.

Group X, claim(s) 11-15, drawn to a composition comprising an effective amount of an antagonist of the HMGB1 protein wherein the HMGB1 antagonist comprises HMGB1 synthetic or natural modulators for the treatment of adverse effects induced by necrotic tissue.

Group XI, claim(s) 16-18, drawn to a method to promote stem cell migration and/or proliferation in cell culture or in vivo comprising the step of exposing cells to an effective amount of the HMGB1 protein or functional parts thereof.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of Group I and II are patentably distinct, because they don't share a special technical feature. For example, composition of group I is comprised of a protein which

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has distinct structure, function, utilities and mode of action compared to composition of group II comprising of an expression vector.

Furthermore, the inventions of groups I-X are distinct from the inventions of group XI because the inventions of groups I-X are drawn to distinct and different compositions while those of group X are drawn to different methods that have distinct and different steps. Accordingly, groups I-XI are not linked by a special technical feature.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R 1.48(b) and the fee required under 37 C.F.R 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

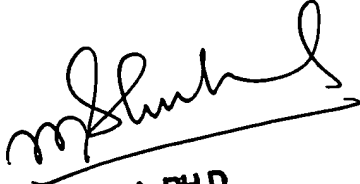
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Magdalene K. Sgagias whose telephone number is (571) 272-3305. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla, can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Magdalene K. Sgagias, Ph.D.
Patent Examiner
Art Unit 1632



RAM R. SHUKLA, PH.D.
SUPERVISORY PATENT EXAMINER